



**UNITED STATES DEPARTMENT OF COMMERCE
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 08/485,066 | 06/07/95 | ENGELHARDT | D ENZ (D5) (C2) |

18N2/0623
ENZO DIAGNOSTICS, INC.
C/O ENZO BIOCHEM, INC.
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EXAMINER

MARSCHER, A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1809

34

DATE MAILED: 06/23/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/486,066

Applicant(s)

Engelhardt et al.

Examiner

Ardin Marschel

Group Art Unit

1809

☒ Responsive to communication(s) filed on

4/29/97 and 5/28/97

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s)

238-297 and 299-338

is/are pending in the application.

Of the above, claim(s)

1-237 and 298

have been canceled.
is/are withdrawn from consideration.

☐ Claim(s)

is/are allowed.

☒ Claim(s)

238-297 and 299-338

is/are rejected.

☐ Claim(s)

is/are objected to.

☐ Claims

are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 1282

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Applicants' arguments, filed 4/29/97 and 5/28/97, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Persuant to 37 CFR § 1.129(a) the finality of the office action, mailed 4/15/97, is hereby withdrawn.

If applicant desires priority under 35 U.S.C. § 120 based upon a parent application, specific reference to the parent application must be made in the instant application. It is noted that this appears as the first sentence of the specification following the title. Status of the parent application (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "Patent No." should follow the filing date of the parent application. If a parent application has become abandoned, the expression "abandoned" should follow the filing date of the parent application.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 238-297 and 299-338 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to covalent attachment of the Sig or PM moieties to the sugar (SM) via the hydroxyls at the 2', 3', or 5' positions of ribose or deoxyribose sugars. This rejection is

maintained as modified from the previous office action, mailed 4/15/97. Applicants argue that a variety of sugars are enabled as being modifiable at all positions therein and allege that the prior art supports this via an exert from a previous amendment of 12/26/96. These are allegations without factual support and therefore non-persuasive in overcoming the rejection, especially considering the factual support in Ward et al. (P/N 4,711,955) in columns 6-7 where Ward et al. discuss at length the many criteria that must be met for the utilities to which nucleosides and nucleotides are put to. Further consideration of the disclosure of Ward et al. reveals detailed chemical guidance for the enablement of a very limited set of nucleotide modifications. This supports the continued maintaining of this rejection. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 238-240, 242, 243, 245, 246, 249, 262, 264, 269, 270, 272-274, 276, 277, 279, 283, 296, 304, 306-310, 312, 313, 315, 319, 329-331, 336, and 338 are rejected under 35 U.S.C. § 102(a)

as being clearly anticipated by Caruthers (1982).

It is noted that the DNA volume 1(2) that discloses Caruthers (1982) is date stamped as being received at the U.S. PTO on March 7, 1982. Caruthers discloses deoxyribose nucleotides that meet the instant claims as having detectable Sig moieties such as dimethoxy-trityl or acetyl moieties as well as a phosphate moiety attached to SM in the form of a phosphine moiety.

Claims 238-243, 245, 246, 249, 255, 256, 262, 264, 265-277, 279, 280, 283, 289, 290, 296, 299, 301-313, 315, 316, 319, 325, 326, 329-333, and 336-338 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Kourilsky et al. (GB 2,019,408).

Kourilsky et al. discloses the preparation of nucleotide, deoxynucleotides, and oligomers thereof with biotin labels as well as mercury and SH groups on page 2, lines 34-52. The polynucleotides attached to a particular nucleotide via the sugar-phosphodiester backbone meets the requirements of the instantly claimed and linked Sig moieties attached to a nucleotide with a phosphate moiety also attached.

No claim is allowed.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 305-3014 or (703) 308-4227.

Serial No. 08/486,066

- 5 -

Art Unit: 1809

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

June 20, 1997


ARDIN H. MARSCHEL
PRIMARY EXAMINER
GROUP 1800